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10/599,119

09/20/2006

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EXAMINER

NATHAN, SHYAM

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

11/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/599,119 | Applicant(s) JANSSENS ET AL. | |
| | Examiner SHYAM NATHAN | Art Unit 1611 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/19/2007, 09/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to the argument sent forth by applicant on 09/18/2008, examiner has withdrawn the restriction requirement for the amended claims sent on 09/18/2008.

Claims 1-7, 19-35 are pending and the subject of the first Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest U.S. effective filing date afforded the instantly claimed invention is 03/21/2006, the filing date of application PCT/EP06/60926.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7 rejected under 35 U.S.C. 102(b) as being anticipated by Chantigny et al. (US Pub No. 2004/0138262; Pub Date: Jul.15,2004) .

Instant claims 1-4, 7 are drawn to a method for the treatment of poultry, a method for the nontherapeutic treatment of poultry for the purpose of reducing the conversion rate of the feed used to raise poultry, or a method for reducing the incidence of ascites in poultry, which treatment comprises orally administering at least one glycine compound to the poultry, which is selected from dimethylglycine, diethylglycine, diethanolglycine,

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dipropylglycine and diisopropylglycine. Wherein, the glycine compound is administered via the drinking water and feed of the poultry. The glycine compound is administered in an amount of between 0.001 and 0.5% by weight of said feed.

Chantigny et al teaches of compounds, methods and compositions which are modulators of the glucocorticoid receptor and as such are useful agents for the treatment of animals for certain inflammatory related conditions which include N,N-dimethylglycine (DMG) [0576-0586, Ex 91-95] in an amount of .075% [0576] (.03 ml of N,N-Dimethylglycine over 4ml of solution). The formulations and dosages is useful for non-human animals such as poultry and can be administered orally in either a liquid or solid state such as water and various poultry feeds.[0353] Furthermore, the concentrated supplements taught by Chantigny et al. (in para 0353) may be added directly to feed to produce a nutritionally balanced, finished feed. The instant claims teaches of a non-therapeutic method and since Chantigny teaches of providing balanced nutrition, this limitation is met. Therefore, the reduction of the conversion rate of feed would be an implicit or inherent property since the same population(chickens) is given the same compound as the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,5-6, 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chantigny et al. (US Pub No. 2004/0138262; Pub Date: Jul.15,2004) and Maria Urdaneta Rincon (A thesis Presented to the faculty of Graduate Studies of The University of Guelph; Mild Feed restriction and Compensatory Growth in the Broiler Chicken; April 2000) as evidenced by (<http://www.healthatoz.com/healthatoz/Atoz/common/standard/transform.jsp?requestURL=/healthatoz/Atoz/ency/ascites.jsp>.)¹

Instant claims 1-6, 19-35 are drawn to a method for the treatment of poultry, a method for the nontherapeutic treatment of poultry for the purpose of reducing the conversion rate of the feed used to raise poultry, and method for reducing the incidence of ascites in poultry, which treatment comprises orally administering at least one glycine compound to the poultry, which is selected from dimethylglycine, diethylglycine, diethanolglycine, dipropylglycine and diisopropylglycine. Wherein the glycine compound is administered via the drinking water and feed of the poultry and the poultry comprises broiler chickens. The glycine compound is, also, administered during a period to poultry

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which is selected and raised in such a manner that over said period the actual feed conversion rate is smaller than 2.50 kg feed/kg body weight gain and/or in such a manner that over said period the growth rate of the poultry is higher than 50 g/day.

Chantigny et al teaches of compounds and compositions which are modulators of the glucocorticoid receptor and as such are useful agents for the treatment of animals for certain inflammatory related conditions (such as ascites , which can be caused by constrictive Pericarditis, which is an inflammation of the pericardium and/or Vasculitis, which is an inflammation of the wall of blood vessels), which include N,N-dimethylglycine (DMG) [0576-0586, Ex 91-95]. The formulations and dosages is useful for non-human animals such as poultry and can be administered orally in either a liquid or solid state such as water and various poultry feeds.[0352] Chantigny et al. does not reducing the incidence of ascites in poultry.

Rincon teaches of the effects of feed restriction on the incidence of ascites in broiler chickens (pg28-30) by reducing the rate of feed, thereby reducing the rate of incidence of ascites in broiler chickens, where the feed: gain ratio or Feed conversion rate is smaller than 2.50. (pg 49)

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to treat ascites using ,N,N-dimethylglycine (DMG). One would have been motivated to treat ascites since ascites is caused by an inflammatory disorder as evidenced by

(<http://www.healthatoz.com/healthatoz/Atoz/common/standard/transform.jsp?requestUR>

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[l=/healthatoz/Atoz/ency/ascites.jsp.](#)) (Ascites , which can be caused by constrictive Pericarditis, which is an inflammation of the pericardium and/or Vasculitus, which is an inflammation of the wall of blood vessels and inflammation of the colon)¹ and Chatigny teaches treating inflammatory disorders using N,N-dimethylglycine (DMG). Further, Rincon teaches ascites is a disorder in chicken and thus one would expect success in the combination.

Conclusion:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHYAM NATHAN whose telephone number is (571)270-5753. The examiner can normally be reached on Mon-Thurs 8:30a.m. - 5:00p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SN

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611